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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Thomas E. Broome

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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

12/13/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/044,368	Applicant(s) BROOME ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-31, 52, 54-56, 58-72, 74-76 and 78-95 is/are pending in the application.
- 4a) Of the above claim(s) 5-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52, 54-56, 58-72, 74-76 and 78-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 12/1/10. The prosecution is reopened to provide a new grounds of rejection under 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 52,54-56,58-72,74-76,78-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. During the prosecution history, the claims were amended to recite that the filtering region comprises "only a single layer of filter membrane". However, upon review of the written disclosure and the originally filed claims, the examiner is not able to find support for this limitation. Note that this limitation is viewed as a "negative limitation", and that any negative limitation or exclusionary provision must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. MPEP 2173.05(i).

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

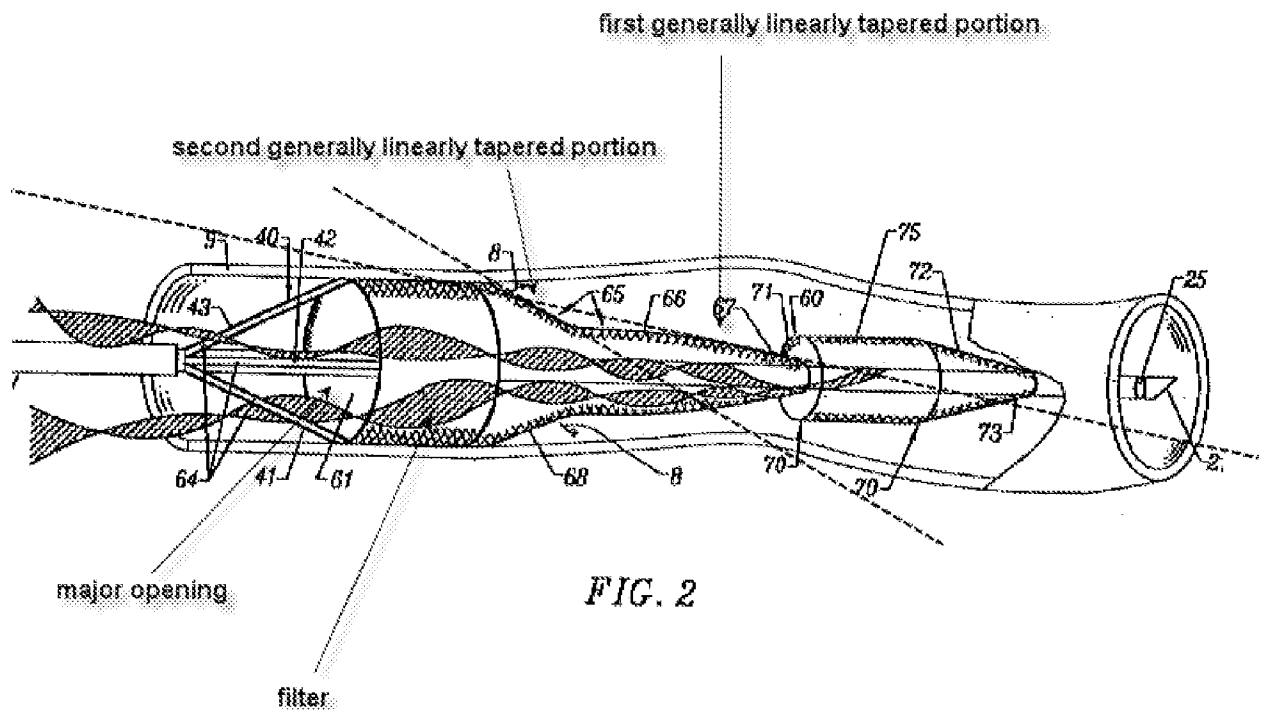
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 52, 54, 55, 58-63, 70-72, 74, 75, 78-83 and 90-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,840,950 to Stanford et al. and in view of US 6,565,591 to Brady et al.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

(claims 52, 58-63, 70-72, 78-83, 92 and 93) Stanford discloses a filter assembly comprising an elongate shaft **20**, a filter disposed and attached to a distal end of the shaft (see attached Fig. 2 below, or even in Fig. 15), the filter including a filtering region (the open portion) and an attachment region; wherein the filtering region includes a major opening defined adjacent the proximal end (see figure below) and is comprised of only a single layer of filter membrane that defines a filter basket and extending between the major opening and the distal end of the filtering region, the filtering region comprising apertures to allow the passage of blood through the filtering region; the filter membrane further comprising a first "generally linearly" tapered portion defining a first angle that is lesser (or different) than a second angle defined by a second "generally linearly" tapered portion (see figure below); wherein the filter has an expanded (Fig. 2) and contracted shape (Fig. 3); wherein the first tapered portion extends at the first included angle for a "substantial length" of the first tapered portion and the second tapered portion extends at the second included angle for a "substantial length" of the second tapered portion.



Stanford also discloses the filter including an expandable frame comprising Nitinol (col. 4, ll. 26); wherein the expandable frame includes a plurality of struts or ribs **41,42,43** that are adapted to bias the filter in an expanded position, wherein the free ends (proximal ends) of the ribs are attached to the opened mouth frame of the filter.

Stanford is silent with regards to the expandable frame disposed within and supporting the first tapered portion and the second tapered portion.

However, the use of expandable frames to support a filter is well known in the art. Brady discloses a filter device, as shown in Fig. 4, that utilizes a frame 100 to support the filter. Note that the frame can have a straight section and a helical section to support the varying shape of the filter. Therefore, it would have been obvious to one

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of ordinary skill in the art at the time the invention was made to modify the device of Stanford to also have an expandable frame within the filter as it would help support the shape of the filter. The expandable frame would be formed to support the shape of the filter, similar to that of Brady.

(claims 54, 55, 74 and 75) The different portions of the filter can be sectioned off to be called the first or second portion, and each of these portion can be selected so that the first portion has a conical shape and the second portion has a frustoconical shape.

(claim 90) The second tapered portion extends proximally from the proximal end of the first tapered portion (see figure above).

(claims 94-95) The only single layer of filter membrane does not fold back on itself.

8. Claims 56 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanford, et al. and Brady et al., as applied to the rejections to claims 52 and 72, and in view of US 5,814,064 to Daniel et al.

Stanford discloses all the limitations of the claim except for the filter membrane comprising a polyurethane. However, Daniel teaches another filter assembly comprising an elongated shaft and a filter membrane (Fig. 18B), wherein filter membrane is made of polyurethane (col. 10, line 44-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use polyurethane in the filter membrane of Stanford because Daniel teaches that polyurethane can be used to form filter membranes. As such, using a specific type of

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material to form the filter membrane would be a mere design choice to one of ordinary skill in the art.

9. Claims 64-69 and 84-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanford et al. and Brady et al., as applied to the rejections to claims 52 and 72, and in further view of US 6,605,102 to Mazzocchi et al.

Stanford discloses all the limitations of the claims except for the filter assembly comprising a retrieval sheath. However, the use of retrieval sheaths is well known in the art, as taught by Mazzocchi.

Mazzocchi discloses a filter assembly comprising an elongate shaft 265, a filter 270 disposed and attached to a distal end of the shaft, the filter including a filtering region and an attachment region (col. 19, line 66 - col. 20, line 8). The filtering region includes a major opening defined adjacent the proximal end (seen in Fig. 18B) and is comprised of a single layer of filter membrane that is folded onto itself to define a filter basked and extending between the major opening and the distal end of the filtering region, the filtering region comprising apertures to allow the passage of blood through the filtering region; the filter membrane further comprising a first tapered portion defining a first angle that is lesser (different) than a second angle defined by a second tapered portion (see attached in the Office Action dated 06/01/2006). The assembly further comprises retrieval sheath C, which is used to retrieve the filter. The filter is also viewed as having a wire that limits the tapering portion because the filter itself is comprised of a wire.

Therefore, one of ordinary skill in the art at the time the invention was made to modify the assembly of Stanford to include a retrieval sheath, as disclosed by Mazzocchi, because it allows the filter device to be removed from the vascular system safely. Furthermore, the modification to include a retrieval sheath will have the dimensions of the retrieval sheath match the dimension of the filter device.

Response to Arguments

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

11. With regards to the 103 rejections, the examiner is maintaining the rejections since the applicant has not complied with the stipulations for overcoming a 102(e) rejection. As state above, this rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/
Primary Examiner, Art Unit 3773